ADSOL RED CELL PRESERVATION SOLUTION SYSTEM IN PLASTIC CONTAINER (PL 146 PLASTIC)- anticoagulant citrate phosphate dextrose (cpd) solution and adsol preservation solution
Fenwal, Inc.

BLOOD-PACK™ Unit with an Integral SEPACELL™ RS-2000/RZ-2000 Whole Blood Leukocyte Reduction Filter for Collection and Filtration of Whole Blood Using CPD/ADSOL™ Red Cell Preservation Solution

Rx only

Contains Sample Diversion System for the collection of whole blood samples for laboratory testing. Also includes the DONORCARE™ Needle Guard.

Integral filter unit intended for leukocyte reduction of whole blood up to 72 hours after blood collection. The leukocyte reduced blood products may then be stored for the maximum allowable dating period.

Instructions for Use

<u>Collection Procedure:</u>

Use aseptic technique.

Notes:

If Sample Diversion System is not used, donor samples may be collected using an alternate method following standard procedures.
Nominal tubing dimensions of product are 0.118” inner diameter x 0.025” wall thickness.

Precautions:

Upon removal of BLOOD-PACK™ unit from the clear plastic overwrap, visually inspect the unit.
Do not use the product if the in-line cannula is broken and/or anticoagulant is present in the sample pouch or in the tubing from the in-line cannula to the sample pouch and donor needle (see Figure 1). Note that condensation in the empty tubing of the BLOOD-PACK unit is expected as a result of the sterilization process.
Do not use unless the solutions are clear.

1. Identify BLOOD-PACK unit using appropriate donor identification system.
2. Donor scale

   Adjust donor scale to desired collection weight.
   Position primary container on the donor scale as far as possible below donor arm.

3. Clamp donor tubing between the needle and Y-junction with hemostat. (This step can be performed prior to step 1 or 2.)
4. Visually inspect the tubing from the in-line cannula to the sample pouch and donor needle, as well as the sample pouch to reconfirm that there is no anticoagulant present.
   Note: Ensure that the sample pouch remains below the donor’s arm.
5. Following blood center procedures, apply pressure to donor’s arm and disinfect site of venipuncture.

6. Remove needle cover per instructions below:

   - Holding the hub and cover near the tamper-evident seal, twist cover 1/4 turn to break seal.
   - Remove needle cover, being careful not to drag the cover across the needle point.

7. Following blood center procedures, perform venipuncture, appropriately secure donor needle and/or tubing and release hemostat.
8. When good blood flow is established, slide the DONORCARE™ needle guard over the needle hub into the engaged position. Leave the front third of the needle hub exposed for access. Stabilize the front of the needle guard to arm with tape. (see Figure 2)
   Note: In difficult collection conditions (e.g. slow blood flow), leave the needle guard disengaged behind the hub during collection. **Engage the needle guard at the end of blood collection. Appropriately secure needle and/or tubing.**
9. Allow the sample pouch to fill with blood according to center procedure. Monitor blood flow into sample pouch.

Notes:

The sample pouch contains an average fill volume of approximately 53 mL with a maximum fill volume of approximately 60 mL when filled to capacity.
If less blood sample volume is required, the flow to the sample pouch may be stopped prior to completely filling the pouch. For example, in order to target a fill volume of approximately 40 mL, fill to the level indicated by the arrows in Figure 1. Ensure the pouch is hanging vertically.
The tube leading from the Y-junction to the sample pouch contains an additional volume of approximately 2 mL.

Precautions:

Do not elevate or squeeze the sample pouch as this could cause blood to backflow from the sample pouch into the collection system.
Once the sample pouch is filled to desired volume, complete steps 10 - 18 within approximately 4 minutes to avoid possible clot formation in the tubing and/or sample pouch.

10. Close the blue clamp on tubing between the Y-junction and the sample pouch.
11. Break the in-line cannula below the Y-junction in the donor tubing to the primary container allowing blood collection to proceed. To completely break the in-line cannula, grasp with both hands. Snap it at a 90° angle in one direction, and then bend it at a 90° angle in the opposite direction. Ensure the in-line cannula is completely broken and that the blood flows freely to the primary container.

Precaution: Failure to break the in-line cannula completely may result in restricted blood flow.

12. Following blood center procedures, mix blood and anticoagulant in the primary container immediately and at several intervals during collection.
13. Following blood center procedures, hermetically seal the tubing between the sampling site and the Y-junction to maintain sterility of the blood collection system prior to removing blood samples.

Warning:

Do not proceed with the remaining steps until the tubing leading to the sample pouch is

hermetically sealed between the sampling site and the Y-junction. To maintain the whole blood collection container as a closed system, the tubing between the sample pouch and Y-junction must be hermetically sealed prior to inserting the access device into the sampling site. Failure to do so may lead to contamination of the whole blood collection.

14. Insert the access device by pushing firmly into the sampling site until the membrane seal is penetrated.

Note: If the access device is assembled such that the outer barrel is screwed onto the Luer, make sure to rotate clockwise upon insertion to avoid barrel detaching from Luer.

15. Open the cap on the access device (if applicable). Hold access device so that the sample pouch hangs down.
16. Directly align the vacuum sample tube with the internal needle in the access device. Insert vacuum sample tube into device.
17. Allow vacuum sample tube to fill with blood then remove from the access device.
18. Repeat steps 16 and 17 until the desired number of vacuum sample tubes have been filled.

Notes:

If the access device needs to be replaced, use a hemostat to clamp the tubing between the sampling site and the sample pouch. Then, grasp base of sampling site with one hand and pull the access device out with the other hand. Firmly insert the new access device. Remove hemostat and continue sampling.

If the access device is assembled such that the outer barrel is screwed onto the Luer, make sure to rotate clockwise upon removal to avoid barrel detaching from Luer.

The access device can only be replaced one time.

Precaution: When replacing access device, be careful to avoid contact with any blood droplets on the Luer or sampling site. Discard used access device appropriately.

19. Collect the appropriate volume based on BLOOD-PACK unit used.
    Note: The volume of anticoagulant is sufficient for the blood collection indicated on BLOODPACK unit ± 10%.

Precaution: Once the desired blood volume is collected, complete steps 20-24 within approximately 4 minutes to avoid possible clot formation in the tubing.

20. Release pressure on the donor's arm. If appropriate, apply hemostat to donor tubing between the needle and the Y-junction.
21. Hermetically seal donor tubing between the in-line cannula and the primary container.
22. **Withdrawal of Needle** (see Figure 3)

Precaution: The needle guard must be held stationary while the needle is withdrawn into it.

a) Place folded sterile gauze over puncture site and hold in place with finger tip without exerting pressure.
b) Hold sides of needle guard near the front, between the index finger and thumb. Pull the tubing smoothly until the needle is locked into the needle guard.
c) Confirm the needle lock by:

- Listen for the 2nd “click” as the needle is drawn into the needle guard.
- Ensure the tubing cannot be pulled through the needle guard.

23. Remove and discard the Sample Diversion System and needle guard into an appropriate biohazardous waste container following established procedures.

Note: Step 24 may be performed prior to step 23 if desired.

24. If the donor tubing is not sealed directly above the primary container, then strip the blood from the remaining donor tubing into the primary container. Mix and allow tubing to refill; repeat once.

Filtration Procedure:

Precaution: Whole blood collected from certain donors may have extended filtration times and the potential for ineffective filtration and leukoreduction.

Note: The time of whole blood filtration may vary depending on processing option selected.

a) Within 8 hours of collection if whole blood is held at ambient temperature.
b) Within 72 hours of collection if whole blood is refrigerated.

25. **Mix unfiltered whole blood thoroughly.** Invert the primary container and hang the filter set such that the filter remains vertical. To achieve maximum flow rate, allow set to hang to full length.

Note: The storage container must remain below the level of the filter during filtration.

26. Inspect all tubing to insure it hangs freely without kinks. Install clamp on vent line and close. (4R4423 clamp recommended)
27. Break the in-line cannula above the filter to start filtration.

Note: Manual or mechanical pressure should not be used to increase the flow rate through the filter.

Note: Tubing below the filter should not be stripped at any time during the filtration process.

Note: If the filtration of whole blood is initiated at ambient temperature and not completed within 8 hours after blood collection, then filtration should be completed between 1 and 6°C.

28. When flow stops, open the clamp and gently squeeze the filtered whole blood container until the air is expelled through the vent line and filtered blood fills the donor segment tubing as desired.
29. Allow filtration to continue until the inlet side of the filter is filled with air.
30. Seal the transfer tubing below the filter. Also seal the vent line tubing directly above the top donor segment number (near the slide clamp). At each location, seal in three places and cut the middle seal being careful to avoid fluid splatter. Discard filter and primary container appropriately.

Note: If a QC sample is desired, thoroughly mix the filtered whole blood and strip the donor segment tubing. Use the last segment (or segments) as the QC sample.

31. Make donor segments. Leave segments attached to the filtered whole blood container.

Component Preparation Procedure:

Note: Platelet concentrates are not intended to be made with this product.

32. ADSOL™ red cell preservation solution should be added to the red blood cells immediately after

the removal of plasma. Preparation of AS-1 red blood cells may vary depending on processing option selected:

a) Within 8 hours of blood collection if whole blood is held at ambient temperature.
b) Within 3 days of blood collection if whole blood is refrigerated.

33. Centrifuge filtered whole blood and secondary containers to prepare CPD red blood cells using the appropriate spin condition.
34. Place filtered whole blood container in plasma extractor, and express plasma into empty TRANSFER PACK™ container by releasing pressure plate and opening closure in tubing of filtered whole blood container.
35. When the desired amount of plasma has been removed, clamp the tubing between Y and plasma container. Seal transfer tubing in three places. Cut the middle seal, being careful to avoid fluid splatter.
36. Suspend ADSOL™ red cell preservation solution container; open closure in tubing and drain contents onto CPD red blood cells. Clamp tubing.
37. Seal transfer tubing in three places near the container of filtered red blood cells. Cut the middle seal, being careful to avoid fluid splatter. **For double BLOOD-PACK unit codes, discard ADSOL solution container. For all other ADSOL codes,** the empty solution container may now be used as a TRANSFER PACK™ container for further component preparation.
38. For further processing of plasma product with multiple BLOOD-PACK units, use standard component processing and storage techniques.

Note: Fresh frozen plasma should be separated from the red blood cells and placed in the freezer at -18°C or colder within 8 hours after blood collection.

39. Mix the ADSOL red cell preservation solution and red blood cells thoroughly, producing AS-1 red blood cells, Leukocytes Reduced.
40. Store suspended AS-1 red blood cells, Leukocytes Reduced, between 1 and 6°C.
41. Infuse AS-1 red blood cells, Leukocytes Reduced, within 42 days of collection.

Warning: Failure to achieve closed system processing conditions negates the extended storage claim and the red blood cell product must be transfused within 24 hours.

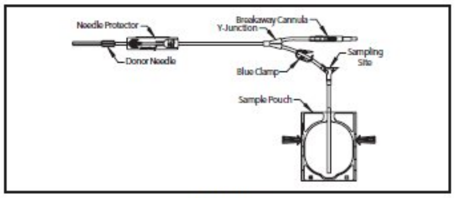


Figure 1

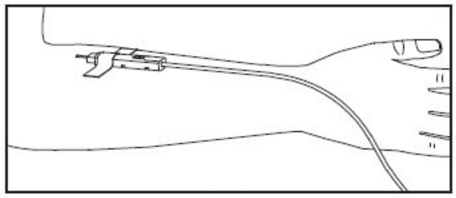


Figure 2

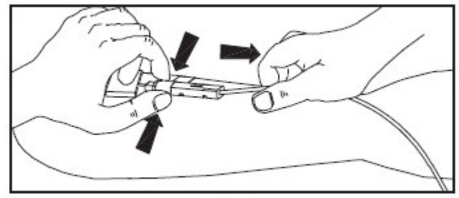
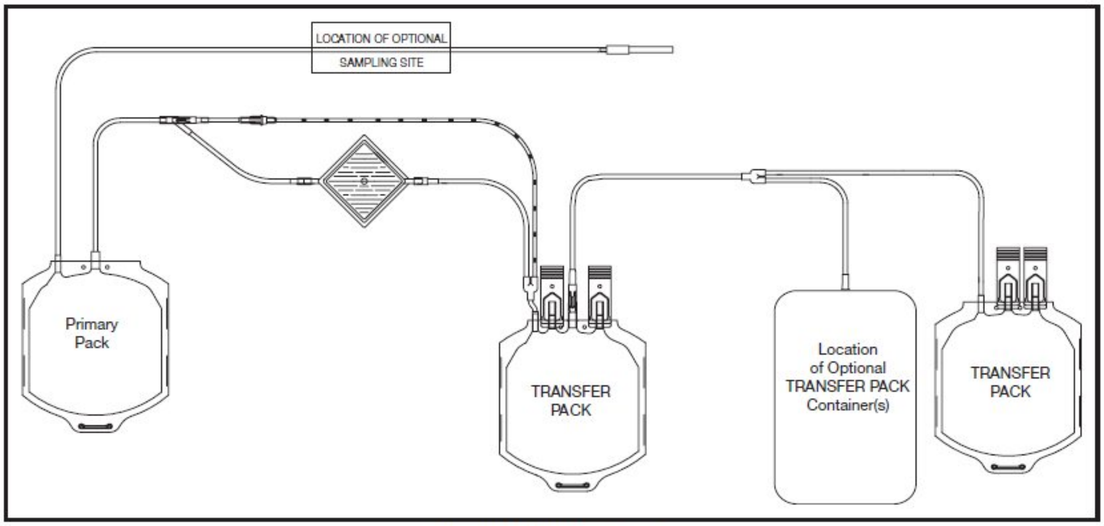


Figure 3



Representative Product Drawing

Store at Controlled Room Temperature.
USP Definition of “Controlled Room Temperature”
United States Pharmacopeia, General Notices.
United States Pharmacopeial Convention, Inc.
12601 Twinbrook Parkway, Rockville, MD

Fenwal, Inc.
Lake Zurich, IL 60047 USA

Made in USA

1-800-933-6925

07-19-04-638 REV: A 03/2010

– Manufacturer

FENWAL, BLOOD-PACK, TRANSFER PACK and ADSOL are trademarks of Fenwal, Inc.

SEPACELL is a trademark of Asahi Kasei Medical Co., Ltd.

DONORCARE is a trademark of ITL Corporation.

PACKAGE/LABEL DISPLAY PANEL

Code 4R3326

10 Units

Fenwal™

Anticoagulant Citrate Phosphate Dextrose Solution, USP (CPD) BLOOD-PACK™ Unit;

TRANSFER-PACK™ Container with ADSOL™ Red Cell Preservation Solution; Integral SEPACELL™ RZ-2000 Whole Blood Leukocyte Reduction Filter

Double For the Collection and Processing of 450 mL Blood

Sample Diversion System, DONORCARE™ Needle Guard, 16 ga. Ultra Thin Wall Needle

Rx only

Each unit consists of a PL 146 Plastic primary container with 63 mL of CPD solution containing 1.66 g Sodium Citrate (dihydrate) USP, 1.61 g Dextrose (monohydrate) USP, 188 mg Citric Acid (anhydrous) USP, 140 mg Monobasic Sodium Phosphate (monohydrate) USP, pH may have been adjusted with sodium hydroxide; one PL 146 Plastic Satellite Container with 100 mL of ADSOL Red Cell Preservation Solution containing 2.2 g Dextrose (monohydrate) USP, 900 mg Sodium Chloride USP, 750 mg Mannitol USP, 27 mg Adenine USP; one empty 400 mL PL 146 Plastic TRANSFER-PACK container; one integral SEPACELL RZ-2000 Whole Blood Leukocyte Reduction Filter and one empty 450 mL PL 146 Plastic TRANSFER-PACK container for the storage of AS-1 red blood cells, leukocytes reduced.

Sterile, non-pyrogenic fluid path.

See instructions for use.

Store at Controlled Room Temperature (refer to direction insert).

Open pouch by tearing across at notch.

Direct handling of product surfaces prior to extended storage in the **foil** pouch, may result in mold growth.

Unused units in open **foil** pouch may be kept up to 60 days by folding and **securing** open end of **foil** pouch to prevent possible loss of moisture, provided:

I) Units are not removed from **foil** pouch, or

II) Unused units removed from **foil** pouch are returned to the foil pouch within 12 hours. Units may be removed from the pouch and returned only once.

Units removed from the **foil** pouch (that are not returned to the pouch within 12 hours) must be used within 4 days (96 hours). Units out of the **foil** pouch for longer than 96 hours must be discarded.

Fenwal, Inc.
Lake Zurich, IL 60047 USA

Made in USA

07-28-05-607 REV: A

Code 4R3326 10 Units

Fenwal

Anticoagulant Citrate Phosphate Dextrose Solution, USP (CPD) BLOOD-PACK™ Unit; TRANSFER-PACK™ Container with ADSOL™ Red Cell Preservation Solution; Integral SEPACELL™ RZ-2000 Whole Blood Leukocyte Reduction Filter

Double For the Collection and Processing of 450 mL Blood

Sample Diversion System, DONORCARE™ Needle Guard, 16 ga. Ultra Thin Wall Needle

Rx only

Each unit consists of a PL 146 Plastic primary container with 63 mL of CPD solution containing 1.66 g Sodium Citrate (dihydrate) USP, 1.61 g Dextrose (monohydrate) USP, 188 mg Citric Acid (anhydrous) USP, 140 mg Monobasic Sodium Phosphate (monohydrate) USP, pH may have been adjusted with sodium hydroxide; one PL 146 Plastic Satellite Container with 100 mL of ADSOL Red Cell Preservation Solution containing 2.2 g Dextrose (monohydrate) USP, 900 mg Sodium Chloride USP, 750 mg Mannitol USP, 27 mg Adenine USP; one empty 400 mL PL 146 Plastic TRANSFER-PACK container; one integral SEPACELL RZ-2000 Whole Blood Leukocyte Reduction Filter and one empty 450 mL PL 146 Plastic TRANSFER-PACK container for the storage of AS-1 red blood cells, leukocytes reduced.

Sterile, non-pyrogenic fluid path.
See instructions for use.

Fenwal, Inc.
Lake Zurich, IL 60047 USA

Made in USA

07-28-05-607 REV: A

Store at Controlled Room Temperature (refer to direction insert).

- Open pouch by tearing across at notch.
- Direct handling of product surfaces prior to extended storage in the **foil** pouch, may result in mold growth.
- Unused units in open **foil** pouch may be kept up to 60 days by folding and **securing** open end of **foil** pouch to prevent possible loss of moisture, provided:
  I) Units are not removed from **foil** pouch, or
  II) Unused units removed from **foil** pouch are returned to the **foil** pouch within 12 hours. Units may be removed from the pouch and returned only once.
- Units removed from the **foil** pouch (that are not returned to the pouch within 12 hours) must be used within 4 days (96 hours). Units out of the **foil** pouch for longer than 96 hours must be discarded.

+M5264R33262.

ADSOL RED CELL PRESERVATION SOLUTION SYSTEM IN PLASTIC CONTAINER (PL 146 PLASTIC)

anticoagulant citrate phosphate dextrose (cpd) solution and adsol preservation solution kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0942-6449

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:0942-6449-02	1 in 1 KIT		

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BAG	63 mL
Part 2	1 BAG	100 mL

Part 1 of 2

CPD

citrate phosphate dextrose solution

Product Information	
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Trisodium Citrate Dihydrate (UNII: B22547B95K) (Anhydrous Citric Acid - UNII:XF417D3PSL)	Anhydrous Citric Acid	1.66 g in 63 mL
Dextrose Monohydrate (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	Dextrose Monohydrate	1.61 g in 63 mL
Anhydrous Citric Acid (UNII: XF417D3PSL) (Anhydrous Citric Acid - UNII:XF417D3PSL)	Anhydrous Citric Acid	188 mg in 63 mL
Sodium Phosphate, Monobasic, Monohydrate (UNII: 593YOG76RN) (PHOSPHATE ION - UNII:NK08V8K8HR)	Sodium Phosphate, Monobasic, Monohydrate	140 mg in 63 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium Hydroxide (UNII: 55X04QC32I)	
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		63 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
NDA	BN811104	03/01/2007	

Part 2 of 2

ADSOL RED CELL PRESERVATION SOLUTION SYSTEM

adsol red cell preservation solution solution

Product Information	
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Dextrose Monohydrate (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	Dextrose Monohydrate	2.2 g in 100 mL
Sodium Chloride (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37)	Sodium Chloride	900 mg in 100 mL
Mannitol (UNII: 3OWL53L36A) (Mannitol - UNII:3OWL53L36A)	Mannitol	750 mg in 100 mL
Adenine (UNII: JAC85A2161) (Adenine - UNII:JAC85A2161)	Adenine	27 mg in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		100 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	BN811104	03/01/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	BN811104	03/01/2007	

Labeler - Fenwal, Inc. (794519020)

Establishment

Name	Address	ID/FEI	Business Operations
Fenwal International, Inc.		091164590	MANUFACTURE(0942-6449)